510(k) Summary
as required by 807.92

K073087

1. Company Identification

TOMEY CORP.
2-11-33 Noritakeshinmachi, Nishi-ku, Nagoya, Aichi, JAPAN 451-0051
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2. Official Correspondent

Tomoko Watanabe (Ms.)
International Dept.

NOV 18 2008

3. Date of Submission

October 31, 2007

4. Device Trade name

NON-CONTACT TONOMETER FT-1000

5. Common/Usual Name

Tonometer and accessories

6. Classification Number

Class II, 86HKX, 21 CFR 886.1930 – Tonometer AC-Powered

7. Predicate Device

Manufacturer	:	Canon Inc.
Trade Name	:	FULL AUTO TONOMETER TX-F
510(k) No.	:	K023816

8. Description of Device

The NON-CONTACT TONOMETER FT-1000 is a tonometer designed using a non-contact measurement system. Air puff gently measures the intraocular pressure of the human eye.

9. Indication for use

The NON-CONTACT TONOMETER FT-1000 is indicated for the measurement of intraocular pressure without contacting the eye to aid in the screening and diagnosis of glaucoma.

10. Technical Characteristics

Comparison table of the principal characteristics of 2 devices in Attachment 1 shows that new and predicate devices are equivalent in the areas of technical characteristics, general functions.

Appendix 1: Comparison Table with Predicate Device

Manufacturer/ Model	CANON TONOMETER TX-F (K023816)	TOMEY NON-CONTACT TONOMETER FT-1000
Type	Non-contact (air-puff) type	Same as TX-F
Indication for Use	The Canon FULL AUTO TONOMETER TX-F is intended to be used for the measurement of intraocular pressure of the human eye.	The NON-CONTACT TONOMETER FT-1000 is indicated for the measurement of intraocular pressure without contacting the eye to aid in the screening and diagnosis of glaucoma.
Measurable range	0 to 60 mmHg Includes automatic shifting between 30/60 mmHg	0 to 60 mmHg (manually changing between 30/60 mmHg)
Measuring increment	1 mmHg	Same as TX-F
Measuring unit	mmHg	mmHg / hPa
Fixation Target	LED(green)	LED(orange)
Operation distance	11.3mm	11.0mm
Observation range	Approx. 15 x 12 mm	Approx. 15 x 9 mm
Alignment	Full Auto/Auto/Manual Full auto R/L, Alignment, Shot Auto Alignment, Shot	Auto alignment Auto shot (These are set independently) Touch alignment
Safety Mechanism	Software Controlled Stopper	Software Controlled Stopper(Same as TX-F) Touch Sensor
Memory	Max. 10 measurements for each eye	Same as TX-F
Data output	RS232C	Same as TX-F
Power-saving system	Available	Same as TX-F
Display	5-inch monochrome CRT monitor	5.7-inch color LCD monitor
Printer	Thermal line printer	Same as TX-F
Chin Rest	Power assisted	Same as TX-F
Power Supply	AC100-240V, 50/60Hz, 0.4-0.8A, Approx.80VA	AC100-240V, 50/60Hz, 85-110VA
Operating range (Movable range)	Front/back: 40mm Left/right: 90mm Up/Down: 30mm	Front/back: 40mm Left/right: 88mm Up/Down: 45mm
Dimensions	280(W)x520(D)x495(H)mm	306(W)x493(D)x463(H)mm
Wight	20.5kg(45.2lbs.)	Approx. 18kg

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tomey Corporation
c/o Kojo Kubo
Comos Corporation
3F, 2-17 Akebono-cho.
Tachikawa
Tokyo 190-0012
Japan

NOV 18 2008

Re: K073087
Trade Device Name: Non-Contact Tonometer FT-1000
Regulation Number: 21 CFR 886.1930
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: HKX
Dated: November 7, 2008
Received: November 10, 2008

Dear Mr. Kubo:

This letter corrects our substantially equivalent letter of November 18, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073087

Device Name : NON-CONTACT TONOMETER, FT-1000

Indications For Use:

The NON-CONTACT TONOMETER FT-1000 is indicated for the measurement of intraocular pressure without contacting the eye to aid in the screening and diagnosis of glaucoma.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear,
Nose and Throat Devices

510(k) Number K073087